

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Edward N. Barthell	Art Unit:	3626
Serial No.:	10/649,127	Examiner:	Sheetal Rangrej
Filing Date:	August 27, 2003	Conf. No.:	4764
Title:	<i>Bio-Surveillance System and Method</i>		

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Edward N. Barthell, MD, declare:

1. I am the inventor of the subject matter of the above-identified U.S. Patent Application ("the invention").
2. I have reviewed the claims of this Application.
3. I conceived in the United States, prior to March 26, 2002, the filing date of U.S. Published Patent Application No. 2003/0187615 and entitled *Methods and Apparatus for Early Detection of Health-Related Events in a Population*, the invention as set forth in the aforementioned claims, and in particular:

A method of detecting a bio-emergency, the method comprising:  
receiving patient health information at a plurality of health care facilities; and  
transmitting, simultaneously with said receiving step, the patient health information to a bio-surveillance network; and  
compiling the patient health information to create compiled health data.  
and

A method of detecting a bio-emergency, the method comprising:  
receiving individual triage patient health information at a plurality of health care facilities from each of a plurality of patients;

on a patient-by-patient basis, electronically recording triage data for that patient in a computer of the associated health care facility, the triage data for each patient containing at least some of the received health information for that patient;

upon recording the triage data for each patient, transmitting at least a portion of the recorded triage data to a computer for one of a plurality of regional repositories automatically and in at least near real-time, the computer for each of the regional repositories receiving triage data from a computer for each of a plurality of the health care facilities;

transmitting triage data to a computer for a centralized recipient from the computers for regional repositories automatically and in at least near real time with its receipt from the computers for the health care facilities;

analyzing the triage data and determining, based on the analysis, whether a possible bio-emergency exists;

communicating, from the centralized recipient, information regarding the possible bio-emergency to at least one of one or more of the regional repositories, one or more of the health care facilities, and other institutions having an interest in responding to a possible bio-emergency.

The following facts and evidence are submitted in support of this declaration.

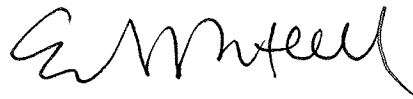
4. I conceived the invention during the fall of 2001, inspired by the terrorism events of that season including the events of September 11, 2001 and the subsequent anthrax scare.
5. I discussed the invention with a number of leaders of the American College of Emergency Physicians (ACEP) at their annual scientific assembly held in Chicago from October 15-18, 2001. Specifically, I discussed the invention at the EM Informatics section meeting, minutes of which are believed to be recorded in the files of ACEP.
6. It is very likely that Mark Crockett, one of the listed inventors of the 2003/0187615 patent application, attended this section meeting.
7. After the ACEP meeting, I co-authored a paper entitled *The Frontlines of Medicine Project: A Proposal for the Standardized Communication of Emergency Department Data for Public Health Uses Including Syndromic Surveillance for Biological and Chemical Terrorism*, and submitted it to the Annals of Emergency Medicine. Although the paper is co-authored by a number of the people that discussed the invention with me at the October ACEP meeting, I solely conceived of the invention. The paper was published as an article in the April 2002, Vol. 39:4 Annals of Emergency Medicine. The article reflects that the paper was received for publication December 18, 2001 and published in April, 2002. (Copy attached as Exhibit A.)
8. The paper and subsequently published article discuss various aspects of the invention, particularly the aspects set forth in the aforementioned claims. Specifically, the last paragraph of page 425 and the first three paragraphs of page 426, along with Figure 1, discuss the idea of receiving triage patient health data, recording said data,

transmitting at least a portion of said data to a regional repository, analyzing said data and communicating information based on the analysis of said and other data.

9. At all times, I proceeded with diligence from the time of my conception of the invention to constructive reduction to practice in the form of a provisional application, filed October 11, 2002, including refining the invention and engaging the services of a patent attorney to investigate the patentability of my invention and preparation and filing of the above-captioned patent application. Evidence of my continued diligence, such as developing uniform standards for the invention, can be found in the Milwaukee Journal Sentinel article dated April 15, 2002 and e-mails dated April 9, 2002 and May 13, 2002. (Copies attached as Exhibit B.)

10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'E. N. Barthell', with a stylized, cursive script.

Edward N. Barthell, MD

# The Frontlines of Medicine Project: A Proposal for the Standardized Communication of Emergency Department Data for Public Health Uses Including Syndromic Surveillance for Biological and Chemical Terrorism

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Dr. Barthell, Dr. Felton, and Mr. Collins are employees and shareholders of Infinity HealthCare, which markets networked emergency medicine information systems under the name EMSys. Dr. Cordell is a Strategic Advisor for New Wave Software, Inc. Dr. Feied and Dr. Smith are founders of and Dr. Handler is the Director of Development of the National Center for Emergency Medical Informatics. Dr. Cochrane is an employee of Emergency Medical Associates, which markets an emergency department information system under the name EDIM.

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The Frontlines of Medicine Project is a collaborative effort of emergency medicine (including emergency medical services and clinical toxicology), public health, emergency government, law enforcement, and informatics. This collaboration proposes to develop a nonproprietary, "open systems" approach for reporting emergency department patient data. The common element is a standard approach to sending messages from individual EDs to regional oversight entities that could then analyze the data received. ED encounter data could be used for various public health initiatives, including syndromic surveillance for chemical and biological terrorism. The interlinking of these regional systems could also permit public health surveillance at a national level based on ED patient encounter data. Advancements in the Internet and Web-based technologies could allow the deployment of these standardized tools in a rapid time frame.

[Barthell EN, Cordell WH, Moorhead JC, Handler J, Feied C, Smith MS, Cochrane DG, Felton CW, Collins MA. The Frontlines of Medicine Project: a proposal for the standardized communication of emergency department data for public health uses including syndromic surveillance for biological and chemical terrorism. *Ann Emerg Med.* April 2002;39:422-429.]

## INTRODUCTION

Recent national events, including the September 11, 2001, attacks on the World Trade Center and Pentagon and subsequent distribution of anthrax by mail, have resulted in intense efforts to pursue improvements in surveillance for chemical and biological terrorism. The nation's emergency departments are a potential source of surveillance information. Existing ED information systems, however, tend to be limited in their capacity and their ability to provide real-time information to public health authorities.

This article describes the Frontlines of Medicine Project and calls for reader comments. The Frontlines

Project is a collaborative effort of emergency medicine (including emergency medical services [EMS] and clinical toxicology), public health, emergency government, law enforcement, and informatics to develop nonproprietary, standardized methods for reporting ED patient data. The Project conceptualizes the rapid deployment of a nonproprietary, vendor-neutral, standards-based regional public health information infrastructure. This infrastructure, composed of interlinked regional public health networks, could be used as a surveillance and "early warning" system to potentially detect chemical and biological terrorism. Although syndromic surveillance is a high public health priority today because of the threat of terrorism, standardizing the transmission of patient data from the front lines of health care could serve to improve the health of the public in other ways in the future.

Although the sense of urgency has recently increased, previous initiatives have recommended improvements in public health surveillance systems. Healthy People 2010 calls for improved surveillance systems as a key objective in the nation's pursuit of improved health status for its citizens.<sup>1</sup> As another example, a national conference in 1994 sponsored by the Josiah Macy, Jr., Foundation noted that shortcomings in ED records limit our capacity to answer many fundamental clinical, epidemiologic, and health service utilization questions about emergency patients.<sup>2</sup>

Despite research that has identified the potential of such a system to improve the public health, no effective system has been widely implemented to collect and analyze population-based emergency encounter data. Several recent incidents provide examples of how a public health information infrastructure that allows data sharing between emergency caregivers and public health authorities could be beneficial:

Milwaukee, WI, 1993—Cryptosporidium contaminates regional water supplies, causing significant morbidity and mortality over a period of months. A retrospective analysis of emergency records showed a markedly increased number of diarrhea cases that began weeks before the deaths but was unrecognized.<sup>3</sup>

Chicago, IL, 1995—A major summer heat wave leads to hundreds of deaths. A retrospective review suggested that an emergency encounter surveillance system could have tipped off authorities of the impending disaster days in advance of the deaths.<sup>4</sup>

Tokyo, Japan, 1995—Sarin gas chemical weapons attacks are perpetrated against the public. Most victims used private transportation to go to hospitals, where caregivers often had little or no understanding of the cause of the symptoms they were trying to treat.<sup>5</sup>

United States, 2001—Several cases of pulmonary anthrax, some resulting in death, are reported in Florida, New York, Washington, DC, and Connecticut. These are traced to deliberately tampered mail. These cases of terrorism underscore the need for rapid information on how to detect and treat potential biological and chemical terrorism agents.

The front lines of health care include EDs, physician offices, and medical clinics. Other potential front line public health data sources include veterinary clinics, prescription and over-the-counter medicine data repositories, and school and work absenteeism reports. Although these data sources all have the potential for public health uses, the initial focus of this Project will be EDs.

EDs are uniquely positioned as surveillance sites because they are open 24 hours each day, are ubiquitous in distribution, and treat huge numbers of patients (>100 million ED visits each year in the United States alone). EDs also direct or are tightly integrated with out-of-hospital care, disaster preparedness and response, clinical toxicology, and regional poison centers.

The large numbers of ED patients, the shift work approach to staffing, and episodic nature of emergency medical care, however, can lead to situations in which insidious problems emerge but are not recognized or reported by individual caregivers. The ability to survey these large number of ED visits, analyze the data for clusters of emerging illnesses, rapidly feedback information to the front lines of health care, and provide just-in-time, point-of-care education has not been standardized or consistently implemented.

## PREVIOUS INITIATIVES

Traditional surveillance efforts in the industry tend to occur by convenience sampling and retrospective review of records at small numbers of facilities, with limited results available only months after the encounters actually occurred. Systematic real-time, population-based data collection and pooling of surveillance data among regional EDs is rare or nonexistent.

A number of federal agencies have initiated a variety of more traditional programs for medical surveillance, particularly with regard to surveillance of injuries and infectious diseases. Data on motor vehicle crash deaths and injuries are collected by the National Highway Traffic Safety Administration (NHTSA) as the Fatal Analysis Reporting System (FARS) and the National Accident Sampling System (NASS). The Consumer Product Safety Commission (CPSC) collects data on injuries and fatali-

ties associated with consumer products (excluding motor vehicles, guns, and a few other products) through the National Electronic Injury Surveillance System (NEISS), which samples data from a series of hospitals.

Three infectious disease sentinel networks are currently funded through the Centers for Disease Control and Prevention (CDC): the Infectious Disease Society of America Emerging Infections Network; EMERGENCY ID NET, a network of academically affiliated EDs; and GeoSentinel, a network operated by the International Society for Travel Medicine. The National Electronic Telecommunications System for Surveillance (NETSS) is used to collect, transmit, and analyze weekly reports of notifiable diseases from state and territorial health offices, Washington, DC, New York City, and US territories. CDC WONDER, which is an online system developed by the CDC that provides access to a variety of reports, guidelines, and public health data, is used as a vehicle for transmission of surveillance files by various CDC surveillance systems.<sup>6-12</sup>

There are limitations with these systems. First, data may be limited (ie, fatal injury statistics but none for morbidity, limitations associated with sampling techniques). Second, there may be difficulty collecting data (ie, retrospective, labor-intensive, manual searches). Third, the distribution of results may be delayed. And fourth, there may be limited or no access to relevant local population-based data for local public health efforts.

Although some of these systems provide significant advances in the use of technology, most are limited in scope. All of them lack the real-time collection, analysis, and reporting capability required to achieve concurrent feedback to providers at the time of emergency patient care. Current processes include mailing or fax transmission of paper-based reports and bulletins and labor-intensive telephone calls between public health offices and clinicians, with resultant communication hampered by time delays and lost messages. In summary, timely communication between public health officers and emergency clinicians remains problematic.

The historical problems with effective collaboration between emergency medicine and public health and the potential for improving the relationship in the future are detailed in a recent review by Pollock et al.<sup>13</sup> Surveillance of diseases, injuries, and health risks is described as 1 of 4 major areas of emphasis. The benefits of sharing health care data among EDs and with public health agencies are currently being investigated. The Indianapolis Network for Patient Care (INPC) in Indianapolis, IN, includes an automated transfer of data regarding reportable diseases

from hospitals to public health authorities.<sup>14</sup> Researchers at Sandia National Laboratories have shown the feasibility of collecting emergency encounter data to detect 6 primary syndromes that might be consistent with bioterrorism.<sup>15</sup> In addition, they have demonstrated how cluster analysis statistical techniques can be effectively used to analyze the data.<sup>16</sup>

The CDC has more recently embarked on the National Electronic Disease Surveillance System (NEDSS) project. This public health initiative provides a standards-based, integrated approach to disease surveillance and connects public health surveillance to the burgeoning clinical information systems infrastructure.<sup>17</sup> NEDSS first release is intended to replace the functionality currently supported by NETSS. Many states have received funding to implement the NEDSS base system, including an integrated data repository (IDR) and an ability to receive data from various Web-based modules. The initial emphasis of NEDSS has been the electronic interchange of laboratory data, and a systematic method for obtaining emergency encounter surveillance data has not yet been defined.

The Information Management Work Group recommended strategies for the application of electronic data systems in emergency medicine.<sup>18</sup> The 4 primary recommendations were:

1. The evolution of standards and uniform data sets should be funded and promoted.
2. Health care information systems should be integrated to meet clinical, management, and research needs.
3. Health care professionals should be trained to use information technologies to transform data into information.
4. Future trends, opportunities, and risks regarding information technologies should be systematically studied.

The Information Management Work Group also recommended that data that has already been collected could be reused and data mined to conduct clinical and public health research, manage patient populations, develop health care guidelines and policies, and educate emergency health care workers.

Schwab and Syme<sup>19</sup> have discussed the importance of community participation in public health issues and advocated a participatory approach to problem solving. Caldwell et al<sup>20</sup> have also emphasized the need for a collaborative approach to solving public health problems. In *Medicine and Public Health: The Power of Collaboration* by Lasker and the Committee on Medicine and Public Health,<sup>21</sup> a collaborative group reviewed the history of poor cooperation between the disciplines of medicine

and public health. The publication also discussed how such collaboration could benefit the health care system in the future. Two of the concepts emphasized are the value of applying a population perspective to medical practice and the importance of using clinical practice to address community health problems.

## CONCEPTUALIZATION

The Frontlines of Medicine Project proposes that a set of standardized tools be developed and implemented to create collaborative regional surveillance systems. The interlinking of these regional systems could permit national surveillance based on ED patient encounter data. Advancements in the Internet and Web-based technologies allow for the deployment of these standardized tools in a rapid time frame.

The Frontlines of Medicine Project proposes a nonproprietary, vendor-neutral, "open systems" approach. The common element is a standard approach to sending messages from individual EDs to regional systems that would then analyze the data received. The Project envisions the creation of oversight entities for each regional surveillance system. For example, a state public health agency, a hospital association, or a regional EMS advisory council could serve this function. In all cases, the Frontlines of Medicine Project recommends this entity be structured to represent multiple stakeholder interests to enhance collaboration.

The work required to designate such an entity can be perceived as a barrier. However, similar entities have successfully been used for other public health purposes requiring collaboration among EDs. Examples of such oversight of shared data include the regional management of ambulance diversions and the INPC project mentioned previously. The regional oversight entity is assigned primary ownership of the data collected and provides a means for control of data distribution to other appropriate parties.

Modern Internet technology allows for flexibility regarding the actual location of the computer servers that store the data. The regional oversight entity may prefer to store a primary copy of the surveillance data on their own or can subcontract this function to a service provider with experience in secure networks, data storage, and back-up procedures. Again, this latter model has been successfully implemented with Internet-based ambulance diversion systems in multiple regions of the country.<sup>22</sup>

Although the data sharing process may serve various purposes in the future, the primary focus of the Frontlines

of Medicine Project is the development of a standardized approach to capturing and sharing surveillance data derived from emergency encounters. The Project does not seek to become a medical data standards organization, because many already exist. Rather, the Project proposes to use existing data standards with a specific approach that can be replicated across the country so that emergency encounter data can be linked to the evolving NEDSS system.

The primary data elements, attributes, and messaging structures for Frontlines of Medicine have been derived from Data Elements for Emergency Department Systems (DEEDS),<sup>23</sup> the National Hospital Ambulatory Medical Care Survey Reason for Visit definitions,<sup>24</sup> the *International Classification of Disease, ninth edition (ICD-9)*,<sup>25</sup> Health Level Seven (HL7),<sup>26</sup> and the Public Health Conceptual Data Model used in the NEDSS project.<sup>27</sup>

Using these underlying data standards, the Frontlines of Medicine Project proposes development of specific extensible markup language (XML) style sheets, such as those defined below, as the basis for sharing data. XML has been identified as a technology for efficiently defining data structures for information exchange.<sup>28</sup> XML uses data "tags" to identify each piece of data sent in a message. An example of the tag at the beginning of a given data element for sex might be <sex>, and an example of the tag at the end of the data element is </sex>. The format allows for ease of interpretation of data strings, even by those without formal information systems training.

The format also provides significant flexibility. Fixed field lengths are not always required, and elements can be easily added to or deleted from a message string without disrupting the ability to translate other elements. It is fully understood that the standards that form the basis of the Frontlines of Medicine effort will evolve over time. For example, HL7 is working to translate DEEDS into an XML format consistent with its other standards efforts. Therefore, system designs will need to be flexible to support periodic updates to other relevant underlying standards, particularly those that enable Frontlines of Medicine tools to work seamlessly with other NEDSS components.

Given the dynamic environment in which Frontlines of Medicine Project systems must operate and the inherent variability in users' willingness to change and support new applications, the project proposes that tools be developed and implemented in a phased approach. Phase one tools depend on clinicians making an active decision to participate in reporting of individual cases or clusters of cases that may represent syndromes consistent with

chemical or biological terrorism. This type of reporting has been encouraged by the CDC<sup>29</sup> but may result in underreporting.<sup>30</sup>

As envisioned by the Project, phase two tools will automatically retrieve surveillance data from computerized information systems used in the day-to-day care of patients. This phase two approach is less likely to cause underreporting. The Frontlines of Medicine Project proposes a "triage-first" strategy for pursuing this type of function. A triage surveillance tool is proposed to document triage data elements during day-to-day care of emergency patients. Copies of these triage data elements, "scrubbed" of individual identifiers, would be sent electronically to the regional surveillance centers. Successful capture of triage data could be followed by additional data capture efforts, such as discharge diagnosis, medication, and disposition data. This would create a system in which the regional surveillance centers continually receive a stream of data from multiple institutions, providing unprecedented ability to monitor emergency encounter activity in real time.

Phase three tools build on the functions described in phases one and two and add a degree of intelligence to the system, such that interactive communication occurs. In systems based on phase three tools, data received from surveillance systems are analyzed and trigger follow-up questions or timely provision of educational materials back to the providers that originally submitted the data.

This type of feedback functionality "closes the loop" and allows for real-time communication and collaboration between public health and emergency providers. The public health network would thus extend beyond just surveillance. Additional public health functions, including the just-in-time delivery of educational materials and a method of rapid communication between the front lines of medicine and public health agencies, could evolve.

As this model develops, the Frontlines of Medicine project has the potential to serve as the standard method of integrating emergency encounter data with the emerging NEDSS project. The integration of Frontlines of Medicine and NEDSS tools is shown schematically (Figure 1).

In summary, the 5 major conceptualizations of the Frontlines of Medicine Project include:

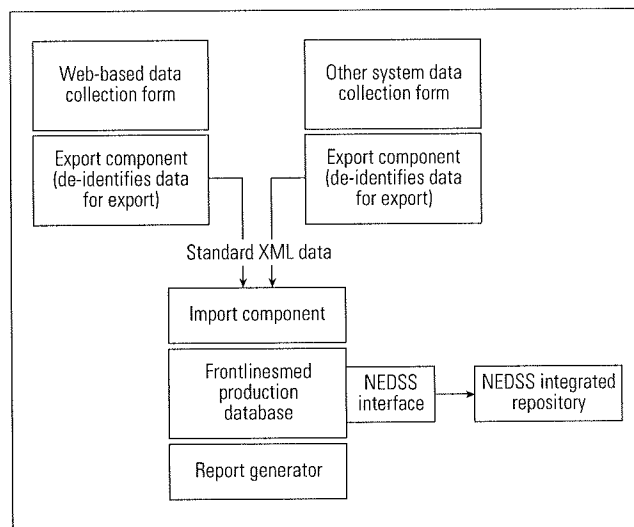
1. Emergency caregivers are encouraged to voluntarily contribute to surveillance by the submission of a universal case report form to a regional public health surveillance entity. The data elements in the form would be reported using the XML style sheet shown in Figure 2.
2. Emergency caregivers are encouraged to voluntarily contribute to surveillance by the use of a universal activ-

ity report form. The data elements in the form would be reported using the XML style sheet shown in Figure 3.

3. Emergency caregivers are encouraged to voluntarily

**Figure 1.**

*Schematic of the Frontlines of Medicine Project–NEDSS interaction.*



**Figure 2.**

*Case report XML style sheet.*

```

<frontlinesmed-case-report>
  <ed-facility-id>
    <namespace-id></namespace-id>
    <universal-id></universal-id>
    <universal-id-type></universal-id-type>
  </ed-facility-id>
  <internal-id>
    <id></id>
    <check-digit></check-digit>
    <assigning-authority></assigning-authority>
    <identifier-type-code></identifier-type-code>
    <assigning-facility></assigning-facility>
  </internal-id>
  <date-time-first-documented-in-ed></date-time-first-documented-in-ed>
  <age></age>
  <sex></sex>
  <chief-complaint>
    <identifier></identifier>
    <text></text>
    <name-of-coding-system></name-of-coding-system>
  </chief-complaint>
  <case-description></case-description>
</frontlinesmed-case-report>
  
```



contribute to surveillance by the use of a universal triage data form. This triage data form may be used as an independent electronic system, served locally or through the Internet, or as a part of an integrated system that serves other purposes. An example of the user interface for this form is shown in Figure 4. The data elements in the form would be reported using the XML style sheet shown in Figure 5.

4. Regional surveillance systems should be formed on the basis of collaboration among providers and public health authorities. Each regional system would include a regional surveillance oversight entity that is responsible for control of the data submitted and generation and distribution of reports to appropriate parties. Patient confidentiality and system security would be rigorously main-

tained consistent with regulations noted in the Health Insurance Portability and Accountability Act (HIPAA).<sup>31</sup>

5. Regional surveillance systems could provide a mechanism for sharing data with other regional systems and the evolving NEDSS project to create a national surveillance system derived from the nation's emergency medical encounters.

We further anticipate that the Frontlines of Medicine Project will result in the development and distribution of actual "open source" software modules that can be shared and used either independently or integrated in other systems.

### THE PROPOSED PROCESS

These initial Frontlines Project recommendations are being developed on the basis of a modification of the nominal consensus methods described by others<sup>32</sup> and are structured to provide rapid cycles of feedback to rapidly deploy standardized tools. Each of the authors has experience in informatics and emergency medical data issues. Each author in turn solicited initial feedback from 3 to 5 others with experience in fields related to this project. This will lead to a rank order process for selecting other participants for a meeting scheduled on April 28, 2002.

Because we believe these public health concepts should engage as broad a representation of ideas and viewpoints as possible, we are soliciting feedback from *Annals* readers, as well as other interested persons from EMS, public health, emergency government, law enforcement, and information technology. Feedback should be

**Figure 3.**

Activity report style sheet.

```
<frontlinesmed-activity-report>
  <ed-facility-id>
    <namespace-id></namespace-id>
    <universal-id></universal-id>
    <universal-id-type></universal-id-type>
  </ed-facility-id>
  <period-start-date-time></period-start-date-time>
  <period-end-date-time></period-end-date-time>
  <activity-description></activity-description>
  <activity-value></activity-value>
</frontlinesmed-activity-report>
```

**Figure 4.**

Conceptualization of a universal triage data form.

Basic Patient Info		History	Vital Signs	Triage Notes
Arrival Date/Time: 10/11/2001 14:37 Name (Last/First): _____ Date of Birth: _____ Age: _____ Years Sex: _____ Home Zip Code: _____ Chief Complaint: Asthma, Anxiety, Blood in urine, Blood per rectum, Blurred vision, Bug bite, Chills		Responsiveness Assessment: Alert Temperature: 0.0 °F °C Oral Rectal Tympanic Axillary Blood Pressure: _____ / _____ Heart Rate: _____ Radial Apical Injury Onset Date/Time: 10/11/2001 14:37 Injury Location Zip Code: _____		
<input type="button" value="Help"/> <input type="button" value="Save"/> <input type="button" value="Cancel"/>				

**Figure 5.**  
Triage report XML style sheet.

```
<frontlinesmed-triage>
  <internal-id>
    <id></id>
    <check-digit></check-digit>
    <assigning-authority></assigning-authority>
    <identifier-type-code></identifier-type-code>
    <assigning-facility></assigning-facility>
  </internal-id>
  <extended-person-name>
    <family-name></family-name>
    <given-name></given-name>
    <middle-name></middle-name>
    <suffix></suffix>
    <prefix></prefix>
    <degree></degree>
    <name-type-code></name-type-code>
  </extended-person-name>
  <dob></dob>
  <sex></sex>
  <home-address>
    <street-address></street-address>
    <other-designation></other-designation>
    <city></city>
    <state></state>
    <postal-code></postal-code>
    <country></country>
    <address-type></address-type>
    <other-geographic-designation></other-geographic-designation>
    <county-code></county-code>
    <census-tract></census-tract>
  </home-address>
  <ed-facility-id></ed-facility-id>
  <date-time-first-documented-in-ed></date-time-first-documented-in-ed>
  <chief-complaint>
    <identifier></identifier>
    <text></text>
    <name-of-coding-system></name-of-coding-system>
  </chief-complaint>
  <first-ed-responsiveness-assessment>
    <identifier></identifier>
    <text></text>
    <name-of-coding-system></name-of-coding-system>
  </first-ed-responsiveness-assessment>
  <first-ed-systolic-bp></first-ed-systolic-bp>
  <first-ed-diastolic-bp></first-ed-diastolic-bp>
  <first-ed-heart-rate></first-ed-heart-rate>
  <first-ed-respiratory-rate></first-ed-respiratory-rate>
  <first-ed-temperature></first-ed-temperature>
  <date-time-of-onset></date-time-of-onset>
  <injury-incident-location-type>
    <identifier></identifier>
    <text></text>
    <name-of-coding-system></name-of-coding-system>
  </injury-incident-location-type>
  <place-of-work-location-type>
    <identifier></identifier>
    <text></text>
    <name-of-coding-system></name-of-coding-system>
  </place-of-work-location-type>
  <triage-comment>
    <text></text>
  </triage-comment>
</frontlinesmed-triage>
```

submitted at the Web site <http://www.frontlinesmed.org>. Comments must be received by April 15, 2002, for inclusion in the meeting. During the meeting, all feedback received at the Web site will be reviewed, ranked, prioritized, and transformed into further recommendations.

Additional work will be needed to more fully evaluate the Frontlines of Medicine recommendations, the effectiveness of data collection systems, how to best analyze the data, and how to present it in a useful fashion to public health authorities. Evaluation should proceed in accordance with updated guidelines recently published by the Epidemiology Program Office of the CDC.<sup>33</sup> We hope that this process will foster a spirit of collaboration to embrace a perhaps unprecedented opportunity to improve the public health information infrastructure in the United States and other nations.

We thank Elizabeth Manchester for her assistance in preparing this manuscript.

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## EXHIBIT B

**Benjamin J. Peirce**

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**From:** Edward Barthell [ebarthell@infinityhealthcare.com]  
**Sent:** Friday, February 16, 2007 11:31 AM  
**To:** Benjamin J. Peirce  
**Subject:** [Fwd: Clarian Press Release Regarding Frontlines Meeting]



Frontlines - Clarian Ann Emerg Med - J Marc Overhage  
Press Rel... Frontlines - A... MD PhD.pdf (14...

----- Original Message -----

**Subject:** Clarian Press Release Regarding Frontlines Meeting  
**Date:** Tue, 9 Apr 2002 15:44:39 -0500  
**From:** William H Cordell, MD <wcordellmd@insightbb.com>  
**To:** <jmills3@clarian.org>  
**CC:** J Marc Overhage MD, PhD <marc@falcon.iupui.edu>, Edward N Barthell MD <ebarthell@infinityhealthcare.com>, Brian F Keaton MD <bfkeaton@earthlink.net>, Roland B McGrath MD <rmcgrath@iupui.edu>, Charles M Shufflebarger MD <CSHUFFLE@clarian.org>

I wanted to brief you about the April 28, 2002 Frontlines of Medicine Project Meeting in Washington, D.C. Because of the urgency in identifying acts of bioterrorism and chemical terrorism, this could be of considerable interest to the press.

Summary: The Frontlines of Medicine Project is a collaborative effort of emergency medicine physicians, poisoning specialists, public health and government officials, law enforcement, and healthcare computer specialists. This collaboration will meet and propose methods and standards for using data from the frontlines of healthcare including ERs to be transmitted and analyzed for public health uses including bioterrorism detection. The meeting will be held Sunday, April 28, 2002 in Washington, D.C. Two Clarian and IU School of Medicine physicians - William H Cordell, MD and J Marc Overhage, MD, PhD - are participants in this collaboration.

I have attached PDF files of the article that appeared in the Annals of Emergency Medicine, a brief summary, and Dr. Overhage's bio.

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Note: The Annals of Emergency Medicine and Mosby publishers have given permission to freely distribute the attached Frontlines article in electronic form.

Dr. Overhage's phone is 630-8685. He can give you more details about his career-long involvement in computers in healthcare. He is also involved in other national initiatives regarding bioterrorism.

Regards, =wc=

\*William H Cordell, MD\*

Clarian e-mail: wcordell@clarian.org  
Clarian phone: (317) 962-8035

## Benjamin J. Peirce

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**From:** Edward Barthell [ebarthell@infinityhealthcare.com]  
**Sent:** Friday, February 16, 2007 11:32 AM  
**To:** Benjamin J. Peirce  
**Subject:** [Fwd: Frontlines Follow-up]

----- Original Message -----

**Subject:** Frontlines Follow-up  
**Date:** Mon, 13 May 2002 16:54:57 -0500  
**From:** William H Cordell, MD <wcordellmd@insightbb.com>  
**To:** J Marc Overhage MD, PhD <marc@falcon.iupui.edu>  
**CC:** Edward N Barthell MD <ebarthell@infinityhealthcare.com>, Jonathan M Teich MD, PhD <jteich@healthvision.com>

I just had a conference call with Ed Barthell and Jonathan Teich discussing where do we go following the Frontlines Meeting. I wanted to brief you on the "grand vision" that is developing:

(1) Develop a "quick and semi-dirty" vocabulary of chief complaints that can realistically be applied at triage in EDs. This would be developed over weeks to months using a Delphi consensus technique/survey. A more rigorous process, likely involving the CDC, would proceed in parallel over a several year timeline.

(2) At the same time the Chief Complaint Vocabulary is being developed, the elements of the XML style sheet will also be determined by the consensus method. (This is expected to be more straight forward.)

(3) We would begin developing a Frontlines "Proof-of-Concept" Consortium involving metropolitan and regional areas that are ready today to begin streaming data. These cities/areas could include southeastern Wisconsin (Ed Barthell et al), Washington-Baltimore (Craig Feied et al), New Jersey (Dennis Cochrane), Boston/Brigham (Jonathan Teich), Portland OR (Andy Zechnich, John Moorhead), Seattle, and Indy/INPC. This would demonstrate that heterogeneous systems can be unified to provide data for public health uses.

(4) We would seek realistic funding to support network development as well as evaluation projects. These evaluation projects could include:

(a) How do emergency staff perceive the impact on ED workflow? (b) A mock drill where 20-30 patients with a factitious syndrome present to the EDs and see if the systems detect them. (3) Test of the system during an actual influenza or other viral epidemic.

The next steps will be to develop and send out the survey (Chief Complaint Vocabulary and ED XML Data Elements) and explore potential funding sources (eHealth, NLM mentioned as possibilities).

Regards, =wc=

\*William H Cordell, MD\*

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